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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jerome T. Hartlaub

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EXAMINER

NAJARIAN, LENA

ART UNIT

PAPER NUMBER

3626

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/002,669	<b>Applicant(s)</b> HARTLAUB, JEROME T.	
	<b>Examiner</b> LENA NAJARIAN	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 27-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-26 and 39-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the Request for Continued Examination (RCE) filed 2/14/08. Claims 12 and 21 have been amended. Claims 1-11 and 27-38 are withdrawn. Claims 12-26 and 39-48 have been examined.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/14/08 has been entered.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 12-15, 17-26, 39-41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Mayer et al. (US 2002/0010597 A1).

(A) Referring to claim 12, Lebel discloses an implantable drug delivery device for delivering at least one drug to a patient comprising in combination (abstract of Lebel):

(a) at least one reservoir each containing at least one drug (para. 60 of Lebel);

(b) a drug scheduling module for determining whether the drug should be replenished (para. 179 of Lebel); and

(d) a telemetry module providing bi-directional communications with an external device (Fig. 3 of Lebel),

wherein the drug scheduling module receives data about the implantable drug delivery device, wherein the data is drug usage information (para. 179 and para. 180 of Lebel).

Lebel does not disclose an appointment scheduling module initiated by the drug scheduling module for automatically, and without scheduling input contemporaneously provided by the patient, scheduling an appointment to replenish the drug in the device and allowing the appointment scheduling module to schedule the appointment.

Mayer discloses an appointment scheduling module initiated by the drug scheduling module for automatically, and without scheduling input contemporaneously provided by the patient, scheduling an appointment to

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replenish the drug and allowing the appointment scheduling module to schedule the appointment (para. 39, para. 27, and para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Mayer within Lebel. The motivation for doing so would have been to provide beneficial features to a patient (para. 27 of Mayer).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(B) Referring to claim 13, Lebel discloses wherein the module contacts via the external device at least one entity, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient (para. 134 of Lebel).

Lebel does not expressly disclose an appointment scheduling module.

Mayer discloses an appointment scheduling module (para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to confirm, track, and keep appointments organized (para. 50 of Mayer).

(C) Referring to claim 14, Lebel discloses the drug scheduling module further receives data (para. 320 of Lebel).

(D) Referring to claim 15, Lebel discloses wherein the drug management instructions is deliver drug to a specified location (para. 204 of Lebel).

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Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(E) Referring to claim 17, Lebel discloses wherein the drug scheduling module includes a drug management algorithm to forecast when a next refill of pump reservoir is required (para. 179, para. 207, and para. 318 of Lebel).

(F) Referring to claim 18, Lebel does not disclose wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is selected from the group consisting of a pharmacy, a caregiver, a physician, a hospital, and the patient.

Mayer discloses wherein the appointment scheduling module is capable of contacting at least one entity for the appointment, wherein the entity is the patient (para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to take into consideration the availability of the patient (para. 50 of Mayer).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(G) Referring to claims 19 and 20, Lebel discloses wherein the implantable drug delivery device is in communication with a computing device, the computing device operatively coupled to the entity (see Fig. 3 of Lebel).

Lebel does not disclose wherein the computing network is the Internet.

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Mayer discloses wherein the computing network is the Internet (para. 9 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to provide the ability to manage health care better (para. 9 of Mayer).

(H) Referring to claim 21, Lebel discloses an implantable drug delivery device, comprising (para. 204 and Fig. 3 of Lebel):

- (a) a housing (para. 204 and Fig. 3 of Lebel);
- (b) a drug reservoir carried in the housing configured to contain a therapeutic substance (para. 204 and Fig. 3 of Lebel);
- (c) a flow control coupled to the drug reservoir for controlling the flow of the therapeutic substance from the drug reservoir through an infusion port (para. 204 and Fig. 3 of Lebel);
- (d) electronics coupled to the flow control and a power source (para. 204 and Fig. 3 of Lebel);
- (e) a telemetry module coupled to the electronics (para. 204 and Fig. 3 of Lebel);
- (f) memory coupled to the electronics, the memory containing pump refill criteria and other refill criteria (para. 204, para. 179, para. 186, and Fig. 3 of Lebel);

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(g) a monitoring module coupled to the memory and the electronics that monitors at least one pump operation variable (para. 204, para. 179, and para. 186 of Lebel); and,

(h) a refill module coupled to the memory and the electronic, the refill module configured to calculate at least one relationship among the pump refill criteria and monitored pump variables, the refill module configured to decide whether a pump refill activity should be reported, and the refill module configured to activate the telemetry module to report a refill activity, wherein the module is adapted to contact via the telemetry module a physician for the scheduling activity (para. 204, para. 179, para. 186, Fig. 3, para. 132, and para. 134 of Lebel).

Lebel does not expressly disclose patient scheduling automatically, and without scheduling input contemporaneously provided by the patient.

Mayer discloses patient scheduling automatically, and without scheduling input contemporaneously provided by the patient (para. 39, para. 27, and para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to provide beneficial features to a patient (para. 27 of Mayer).

Insofar as the claim recites “selected from the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

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(I) Referring to claim 22, Lebel discloses wherein the refill module determines whether an appointment is necessary to perform a pump refill (para. 179 and para. 186 of Lebel).

Insofar as the claim recites “the group consisting of,” it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 23, Lebel discloses wherein the refill module communicates via the telemetry module with an external device (Fig. 3 of Lebel).

(K) Referring to claim 24, Lebel discloses contacting the patient via the telemetry module (para. 134 and Fig. 3 of Lebel).

Lebel does not disclose wherein the scheduling module contacts the patient for the appointment scheduling.

Mayer discloses wherein the scheduling module contacts the patient for the appointment scheduling (para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to take into consideration the availability of the patient (para. 50 of Mayer).

(L) Claims 25 and 26 repeat the same limitations of claims 19 and 20, and are therefore rejected for the same reasons given for those claims.

(M) Referring to claim 39, Lebel does not disclose wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment.

Mayer discloses wherein the appointment scheduling module comprises a scheduling management algorithm capable of being enabled by the drug scheduling module to initiate the automatic scheduling of an appointment (para. 39 and para. 50 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to provide beneficial features to a patient (para. 27 of Mayer).

(N) Referring to claim 40, Lebel does not disclose wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment.

Mayer discloses wherein the scheduling management algorithm receives predetermined scheduling preferences upon being enabled to initiate the automatic scheduling of an appointment (para. 50 and para. 16 of Mayer).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to take into consideration the availability of the patient (para. 50 of Mayer).

(O) Referring to claim 41, Lebel does not disclose wherein the predetermined preferences are holiday and work schedules.

Mayer discloses interacting with the patient's own calendaring system (para. 50 of Mayer).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Mayer within Lebel. The motivation for doing so would have been to take into consideration the availability of the patient (para. 50 of Mayer).

While Mayer does not mention holiday and work schedules, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to include the aforementioned features since these are common events that would need to be worked around in order for a patient to attend an appointment.

Insofar as the claims recite "selected from the group consisting of," it is immaterial whether or not the other elements are also disclosed.

(P) Claims 44-46 repeat the same limitations as claims 39-41, and are therefore rejected for the same reasons given above.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Mayer et al. (US 2002/0010597 A1), and further in view of Akers et al. (6,112,182).

(A) Referring to claim 16, Lebel and Mayer do not disclose wherein the drug scheduling module receives drug management data selected from the group consisting of name of drug manufacturer, date drug was manufactured, and name of pharmacy carrying the drug.

Akers discloses wherein the drug scheduling module receives drug management data such as name of drug manufacturer (col. 5, lines 18-21 of Akers).

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At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Akers within Lebel and Mayer. The motivation for doing so would have been for a comprehensive drug record (col. 5, lines 18-21 of Akers).

Insofar as the claim recites "the group consisting of," it is immaterial whether or not the other elements are also disclosed.

6. Claims 42-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al. (US 2002/0016568 A1) in view of Mayer et al. (US 2002/0010597 A1), and further in view of Cummings, Jr. et al. (US 6,345,260 B1).

(A) Referring to claim 42, Lebel and Mayer do not disclose wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment.

Cummings discloses wherein the appointment scheduling module records whether all entities being scheduled have acknowledged acceptance of the scheduled appointment (col. 8, lines 38-57 of Cummings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cummings within Lebel and Mayer. The motivation for doing so would have been to provide a tentative booking confirmation of the appointment (col. 8, lines 38-57 of Cummings).

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(B) Referring to claim 43, Lebel and Mayer do not disclose wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment.

Cummings discloses wherein the appointment scheduling module searches for another appointment time in the event that not all entities being scheduled have acknowledged acceptance of the scheduled appointment (col. 6, lines 16-18 of Cummings).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Cummings within Lebel and Mayer. The motivation for doing so would have been to find other available appointment times and dates (col. 6, lines 16-18 of Cummings).

(C) Claims 47-48 repeat the same limitations as claims 42-43, and are therefore rejected for the same reasons given above.

### ***Response to Arguments***

7. Applicant's arguments filed 2/14/08 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 2/14/08.

(1) Applicant argues that Lebel does not disclose an appointment scheduling module initiated by a drug scheduling module. Further, the external communication device of Lebel is not an appointment scheduling module that is

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within the implantable drug delivery device as claimed in claim 12 of the present application. There is no teaching or suggestion in Mayer that the scheduling of appointments is initiated by a drug scheduling module or any equivalent thereof.

(2) Applicant argues that Lebel teaches an external device that sounds an alarm to remind the patient to schedule an appointment, and does not disclose a scheduling module that initiates a telemetry module to schedule an appointment. At best, the system of Mayer only schedules an appointment with scheduling input contemporaneously provided by the patient.

(A) As per the first and second arguments, the Examiner respectfully submits that Mayer was relied upon for the feature of an *appointment* scheduling module (see para. 39, para. 27, and para. 50 of Mayer). Lebel discloses a drug scheduling module for determining whether the drug should be replenished and wherein the drug scheduling module receives data about the implantable drug delivery device (see para. 179 and para. 180 of Lebel). As such, it is readily apparent that Lebel can detect that there is a need for the scheduling of a refill. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the Examiner disagrees that Mayer only schedules an appointment with scheduling input contemporaneously provided by the patient. The Examiner respectfully submits that at the time of scheduling, Mayer

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automatically schedules an appointment (see para. 50 of Mayer). As such, it is readily apparent that there is no input from the patient at that point in the scheduling process.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571)272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. N./  
Examiner, Art Unit 3626  
In  
3/3/08

/Robert Morgan/  
Primary Examiner, Art Unit 3626